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**ISO-9000: EFFECTS ON THE GLOBAL MARKETPLACE
AND
CONTRACT RELATIONS WITH THE U.S. DEPARTMENT OF DEFENSE**

C. W. Stoddard
Major, United States Marine Corps
B.S., Montana State University, 1984

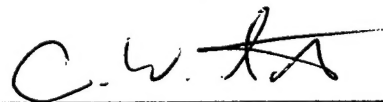
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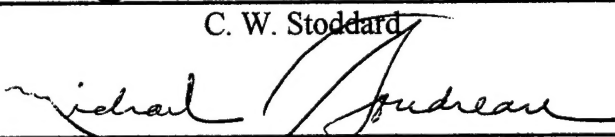
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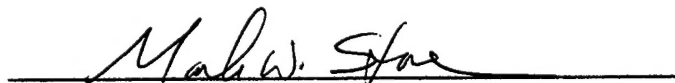


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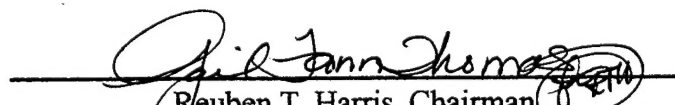
Approved by:



M. W. Boudreau, Thesis Advisor



Mark Stone, Associate Advisor



Reuben T. Harris, Chairman
Department of Systems Management

ABSTRACT

The purpose of this study is to determine how the direction toward standardizing quality control systems worldwide, specifically ISO-9000 criteria, is affecting business procedures both internally (operations) and externally (global marketing). A methodology for determining current opinions and business practices concerning ISO-9000 certification was developed by reviewing the most current literature available and through personal interviews with various quality systems managers of ISO-9000 certified companies. Areas of focus throughout the research were: ISO-9000 capabilities for company certification, current U.S. Government initiatives concerning standardization and contracting, the cost-benefit objectives of certification, real-time perceptions of certified companies and the effects that ISO-9000 has had on global marketing of products. The range of data were analyzed and conclusions drawn with respect to current international conditions of standardization and how Government contract actions incorporate non-MILSPEC quality systems. Recommendations include: immediate update of the FAR to incorporate the guidance issued by the Secretary of Defense concerning use of commercial quality assurance systems in Government contract actions and follow-on studies on the continued effects of international standardization as the IOS proceeds into the next century.

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I. INTRODUCTION

A. BACKGROUND

Since the mid-1990's, there has been a significant movement in industry to standardize the way industry obtains quality assurance. A leading factor in this movement is the ISO-9000 standards—a program initiated by the International Organization for Standardization (hereafter referred to as ISO) that standardizes quality assurance systems or processes. Reaching the requirements of ISO-9000 can lead to a certification process that can be beneficial to the industry in the eyes of the customer and supplier, such as the Department of Defense and other major purchasers of goods.

What was once an opportunity to improve internal systems in hopes of producing a higher quality end product by adopting ISO-9000 techniques appears to have become, in the eyes of some, a requirement to be able to do business in today's national and global marketplace. Depending upon the size of the industry or company, the willingness or ability to comply with ISO-9000 can be costly.

Some opinions in industry are of the notion that ISO-9000 is another passing fad and something else to waste valuable time and resources on when acceptable methods are already in place. Does ISO-9000 have a place in industry and will it prevail over previous attempts at standardizing?

B. RESEARCH OBJECTIVE

The goal of this research is to determine how the apparent direction toward standardizing quality control systems worldwide, specifically ISO-9000 criteria, is affecting businesses. Subsequent changes that result from ISO-9000 certification within the business organization and how it affects contract actions with the U. S. Government are explored. Through research of written articles and personal interviews, an evaluation of any benefits to industry in pursuing these international standards is conducted. Development of constructive recommendations concerning adoption of standardized quality systems follows.

C. RESEARCH QUESTIONS

The primary research question is: Is ISO-9000 certification a necessary tool to increase a company's competitive stature in seeking out both DoD and commercial contracts or are there suitable quality process system alternatives available to industry that will ensure acceptable product quality? Secondary questions that result from analysis of the primary question data are as follows.

- What is ISO-9000 and how can it benefit a company?
- What is the impact of ISO-9000 on Government contracting and global business?
- What are the positive/negative factors a company must consider if choosing to adopt the ISO-9000 Quality Management System (QMS)?
- What is the value to businesses that adopt the ISO-9000 QMS?

D. SCOPE OF RESEARCH

The main focal point of the thesis is an analysis to ascertain whether or not ISO-9000 series certifications make a company more competitive in today's

global business environment. The thesis does cover service industries. Rather, the focus is on industries whose quality systems produce hard goods; primarily those purchased by DoD and other large buyers.

E. METHODOLOGY

The methodology used in this thesis research consists of the following steps:

- Detailed literature review of current books, periodicals, Defense Acquisition Deskbook and the Internet.
- Face to face interviews with local industries in the San Jose, California area that have already received ISO-9000 certification. Prior to all interviews, the list of questions was available to the prospective interviewees. The majority of the questions focused upon how each company perceives cost/benefit of ISO-9000 adoption and whether or not these new standards are proving to be economically beneficial.
- Analysis of current literature that revealed both pro and con opinions of quality systems experts concerning ISO-9000 certification.
- Examination of current DoD requirements on quality systems and how ISO-9000 integrates into these requirements.
- Using the literature reviews and data collected from interviews, an analysis is done and recommendations are proposed as to future DoD policy on the use of ISO-9000 standards.

F. EXPECTED BENEFITS

This research provides insight into whether or not the DoD should aggressively require mandatory compliance with ISO-9000 standards and provide additional information on ISO-9000 trends in global business. If cost/benefit perceptions in industry are positive or negative or if there are suitable substitute quality management systems available to industry, the research gives a clearer picture on possible directions that the standardization issue can take.

G. CHAPTER OUTLINE

Chapter I gives a brief overview of where this thesis is headed. Chapter II gives a detailed background of ISO-9000 and how certification can benefit business. Chapter III explores the impact that ISO-9000 is having on the global marketplace and how the DoD is incorporating this quality system into its contract actions. Chapter IV takes into account the many variables that present themselves to business taking on the challenge of ISO-9000 certification. Chapter V focuses on the value judgments of ISO-9000 certified companies and how ISO-9000 has contributed to their business efforts. Chapter VI provides an analysis of the research data, leading to the conclusions and recommendations in Chapter VII.

II. ISO-9000 OVERVIEW

This chapter provides the reader with an historical background of the emergence of the ISO-9000 series quality standards. A brief explanation follows of ISO-9000 and its subdivisions (9000 to 9004), the definition of QS-9000 and its relationship with ISO-9000, and the major requirements of a complete quality system as required by ISO-9000. The purpose of ISO-9000 and the capabilities that an ISO-9000 series certification provides to a business unit are also explained.

A. HISTORY

The International Organization for Standardization (commonly recognized as ISO) was founded in 1946 in Geneva, Switzerland to encourage the development of standardized systems and procedures for industries involved in production of goods and services. From that small beginning, membership extends to more than 150 countries worldwide today. The American National Standards Institute (ANSI) is the representative institution for the United States within ISO. [11]

Early standardization requirements began with military procurement actions in an attempt to control the documentation processes of military contract suppliers. From these early requirements through years of modification and transformation, there has been an evolution into our modern-day quality systems standards.

The current ISO-9000 standards have their roots in, and are a culmination of, several worldwide military published specifications. Examples are NATO's 6-49 published in 1945, MIL-Q-9858A (Quality Program Requirements) published in 1963, MIL-I-45208A (Inspection System Requirements), U.S. Air Force Standard AF 5923, NATO Allied Quality Assurance Publications (AQAP) and the British DEF STAN OS-21 and 05-8. The British model for quality systems, British Standard (BS) 5750 was first to incorporate procedures for commercial production activities. The ISO, in 1979, formed a Technical Committee (TC 176) to work on the issues of the growing amount of individual national standardization systems, which were causing confusion amongst nations and the increase in quality demands by customers on suppliers. In 1987 the ISO published the ISO-9000 model, based on the committees' investigations; it was predominantly structured on the BS-5750 standard system. [11][12]

B. ISO-9000/QS-9000 Quality Management System

The ISO-9000 series can be defined as a set of quality management standards (not product specifications) that are used to incite quality assurance methods. These standards provide a systematic approach for industry to follow in managing their processes. [37]

The equivalent Quality Management System (QMS) standards of ISO-9000 in the United States are the ANSI Q-9000 series standards. Virtually the same in technical construct, Q-9000 is a modified version, developed after the

ISO-9000 standards, with the appropriate U.S. terminology, language differences and a few additional elements. [11]

QS-9000 standards are the basis for quality system requirements borne out of the North American automotive industry. They were developed by the Chrysler/Ford/General Motors Requirements Task Force to provide for continuous improvement with an emphasis on preventing defects and reducing waste and variation within the supplier base, with applications to all internal and external supply sources of production, service parts and materials.

QS-9000 contains the 20 elements of ISO-9001 section 4 listed below plus 3 additional elements. [24] [13]

For the purposes of this paper, the term ISO-9000 will be used to avoid confusion.

ISO-9000 consists of five subdivisions:

- ISO-9000: Quality Management and Quality Assurance Standards. This provides supporting guidance in the selection and use of ISO-9001 through 9004.
- ISO-9001: Quality Systems. A model for Quality Assurance in Design and Development, Production, Installation and Servicing.
- ISO-9002: Quality Systems. A model for Quality Assurance for Production and Installation.
- ISO-9003: Quality Systems. A model for Quality Assurance in Final Inspection and Testing.
- ISO-9004: Quality Management and Quality System Element Guidelines. This subdivision provides greater detail guidance for each of the three systems models and provides guidance on internal auditing. [10]

ISO-9001 is the predominant model that companies, who are involved in developing and producing products, base their certifications upon. The ISO-9001 Quality Management System consists of 20 elements which an organization must comply with, and completely document all the processes that are included within the elements, in order to become eligible for certification. Figure 1 lists the elements of ISO/QS-9001.

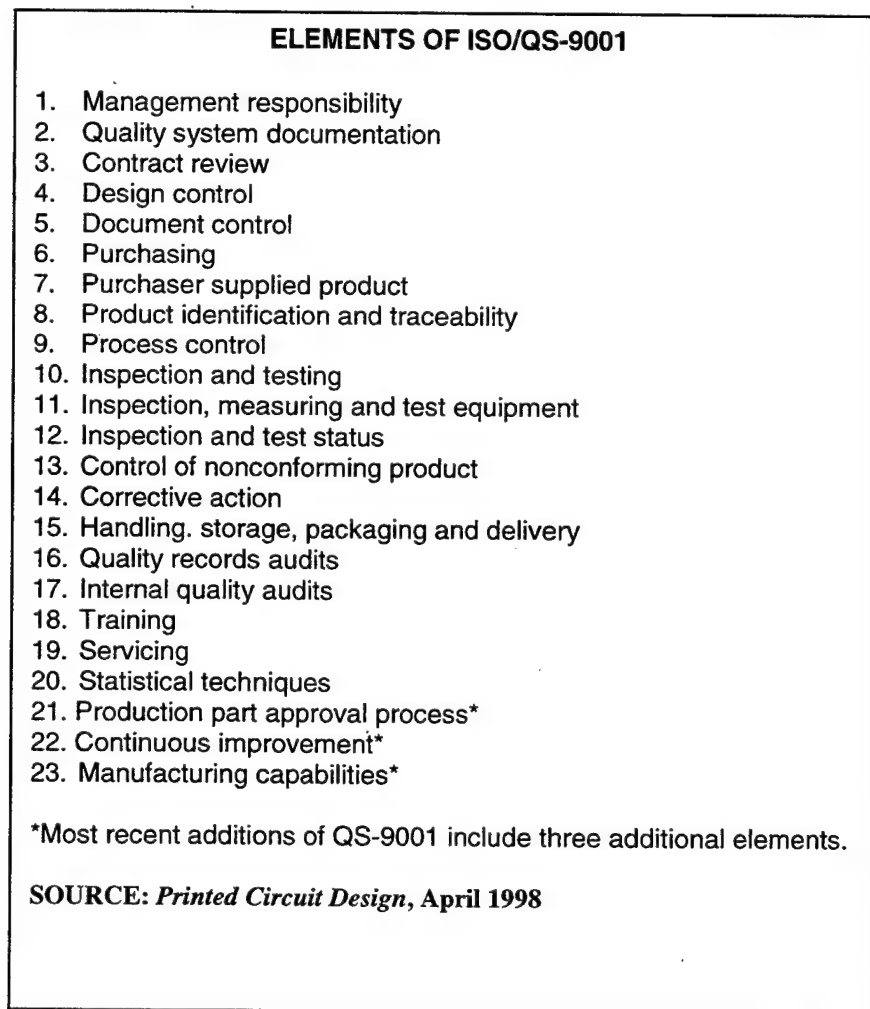


Figure 1 Essential elements of ISO/QS-9001

C. PURPOSE OF ISO-9000 QMS

Industry attempts at managing their products' quality have taken an evolutionary path. This evolution in quality has gone through several phases. Initially inspection systems resided at the tail end of the production line and measured product against "keep or reject" product criteria. The next phase entailed "in-process" determinations of product quality utilizing team effort and responsibility. The current phase of this evolutionary path has produced quality management systems such as ISO-9000. This concept of quality is completely integrated into the business' organizational framework—processes and each separate department, not exclusively in the production side of a business. A quality management system is implemented within the organization with the expectation of gaining consistency in the performance standards to be achieved for the final product. The quality management system should provide the mechanism or catalyst for continually improving upon product and service quality.

[32]

D. CAPABILITIES

Common conceptions of what ISO-9000 certification can provide to the prospective user are varied. The extent and degree of importance that these capabilities can assume are also open to interpretation. ISO-9000 can provide an organization an internationally recognized means to communicate a common credible quality management system that contractual business partners, both current and prospective, can understand and rely upon to deliver an acceptable

product. The ability for a business to project its products' capabilities to its customers and provide positive assurances that their processes are world-class, undergoing continual improvement and capable of attaining goals of quality performance, are as important as producing the items themselves. [12]

Continuous improvement of quality through prescribed internal auditing (common to all sub-sets of ISO-9000) of processes as well as external auditing (certification compliance) is a major factor that adoption of ISO-9000 is expected to provide. [26] A result of the continuous improvement process is the ability of the company to recognize and remove non-value added processes and procedures. This not only has the effect of streamlining some business efforts it is very often a positive cost cutting consequence. Both customers and suppliers can be fairly certain that an ISO-9000 certified company is consciously trying to improve their products' quality, however, a certification is by no means a *carte blanche* avenue to acceptance in the business world. Exceptions and recognition biases do exist and are discussed in more detail in succeeding chapters.

Suppliers that are ISO-9000 certified provide customers the option of reducing, or eliminating altogether, on-site inspections or audits. This reduces costs for both entities, saving valuable resources in time, money and personnel.

In today's marketplace a product is only as successful as the combination of the need for the product, the products' quality in fulfilling performance requirements and the ability of the producer to sell his product by strategic

marketing. Use of globally accessed information systems such as ISO-9000 registry databases on the World Wide Web for exposure to prospective clients, is a prime example of a useful strategic marketing tactic. ISO-9000 cannot help in, creating a market need for a product or a business marketing strategy decision, but adoption of one or more of the ISO-9000 models can increase the probability of quality product recognition in the eyes of customers.

III. DOD AND THE GLOBAL MARKETPLACE

Chapter III provides information to the reader on how ISO-9000 QMS affects U.S. Government contract actions and the impact it has on global trade. Areas of information provided are current DoD initiatives, U.S. Government export trade policies, the infrastructure of standardization bodies in the U.S. and the European Union (EU), and recent statistics on ISO-9000 worldwide certifications.

A. DOD INITIATIVES

Within the DoD there has been a shift of focus concerning product quality from the "in process" evaluation of conformance to that of the processes which control the final outcome of the product. Achieving quality must be the objective in all of the actions of an acquisition or procurement. Effective implementation of the processes of source selection, risk management, system engineering, management of suppliers, manufacturing and testing, and contract administration all contribute to achieving a quality end product. [5]

This new focus is evident by several memoranda issued by Government officials who are intimately involved in procuring goods for the Armed Services. The Secretary of Defense's (SECDEF) office, beginning in 1994, issued the following directives.

SECDEF Memorandum of June 29, 1994, "Specifications and Standards—A New Way of Doing Business," gave guidance to Department of Defense personnel involved in acquisitions and contracts. It directed the use of

commercial practices, performance specifications and development of streamlined procurement processes to allow contractors the flexibility to use quality management systems of their choice. [34] The prescribed, but not mandated, minimum design quality management system was one that adhered to the 20 elements of (ANSI/ASQC-9000 (ISO-9000)) standards. [5]

SECDEF Memorandum Of 6 December 1995, "Common Systems/ISO-9000/Expedited Block Changes," and the USD (A&T) Memorandum of 8 December 1995 gave additional guidance in the use of single processes within a contractor's facility. These two memos were created in an effort to speed up the shift from military specifications (MIL-Q-9858A) to commercial, ISO-9000, or equivalent quality standards and to remove multiple quality, business or technical processes that overlapped in effort and outcome. By directing these changes, the SECDEF allowed block changes to existing contracts in the areas of management and manufacturing requirements. It was now incumbent upon the contractors to submit concept papers and proposals to streamline contracts using alternative specifications and standards. [33]

The overall intended result of these memoranda was to simply reduce costs to the Government by letting industry come up with constructive, innovative ways to implement commercial business practices in a quick manner, thereby moving away from slow "business as usual" methods of the past. It must be noted that the USD (A&T) Memorandum specifically mentions that shifting from MIL-Q-9858A to ISO-9000 is not necessarily a cost saving contract action and,

therefore, could be made in an expeditious manner without the requisite paperwork and proposals of more detailed changes to contracts. [25]

B. GOVERNMENT CONTRACT REQUIREMENTS

The Government's policy on the application and use of commercial quality standards is addressed as follows.

The elements of ANSI/Q-9000 represents a framework for a basic quality system, however, they should not be viewed as the only commercial quality specifications available, or the most effective basic quality system requirements. Many other industry quality standards (i.e. the auto industries [SIC] QS-9000) exist and are potentially more effective than the ISO or ANSI 9000 quality standards. It is therefore in the DOD policy to cite the DOD requirement with the words "or equivalent" to allow offerors the flexibility to propose their own equivalent quality system. Quality systems that satisfy DOD acquisition needs should be recognized whether they are modeled on military, commercial, national, or international standards. [2]

The Federal Acquisition Regulation (FAR) Subpart 46.2 Contract Quality Requirements gives those specific requirements to contracting officers that must be included in procurement contracts.

FAR 46.202-1, Contracts for Commercial Items, states that "when acquiring commercial items (see Part 12), the Government shall rely on the contractor's existing quality assurance systems as a substitute for Government inspection and testing before tender for acceptance unless customary market practices for the commercial item being acquired include in-process inspection. Any in-process inspection by the Government shall be conducted in a manner consistent with commercial practice."

When contracts involve large dollar amounts or those of increased complexity, there are additional requirements under the FAR. These are addressed in FAR 46.202-4 -- Higher-Level Contract Quality Requirements.

- (a) Higher-level contract quality requirements are contained in the clause prescribed in 46.311. Such requirements are appropriate in solicitations and contracts for complex and critical items (see 46.203 (b) and (c)) or when the technical requirements of the contract are such as to require--
 - (1) Control of such things as work operations, in-process controls, and inspection; or
 - (2) Attention to such factors as organization, planning, work instructions, documentation control, and advanced metrology.
- (b) If it is in the Government's interest to require that higher-level contract quality requirements be maintained, the contract shall require the contractor to comply with a Government-specified inspection system, quality control system, or quality program (e.g., MIL-I-45208*, MIL-Q-9858*, NHB 5300.4(1B), NHB 5300.4(1C), FED-STD-368, or ANSI/ASME NQA-1). The contracting officer shall consult technical personnel before including one of these specifications in a contract. [4]

* As of October 1998, the FAR had not been updated to reflect that these two MIL standards have been cancelled.

Not only will the contracting officer consult the appropriate people; he now needs to be granted a waiver, as directed in the aforementioned SECDEF Memo

of 29 June 1994, from the Milestone Decision Authority appropriate to the type of acquisition category the contract will serve.

Former ways of procuring products and a transition from MIL Specs/MIL STDs to commercial practices and ISO-9000 QMS entails some fundamental changes on the part of contracting officials. A Statement of Objective (SOO) replaces the Statement of Work (SOW) that was generated by the military Service buyer. This change allows the product supplier to apply his expertise, capabilities and innovative ideas in design, fabrication, manufacturing, and assembly techniques in fulfilling the product requirements. In a reverse of the previous process order, the supplier will now respond to the buyer's SOO with a SOW. [1] By going to commercial specifications such as ISO-9000, the supplier now can disengage himself from some of the prohibitively detailed military specifications of the past, providing resource savings such as time and money.

If the contractor now has the ability to use a quality management system of his choosing, and the Government has indicated that ISO-9000 is one of the systems that is suitable, should not the Government provide funding to the contractor for his cost of becoming ISO-9000 certified? Unfortunately for product suppliers, the answer is usually no. Since the wording of the various directives and FAR requirements do not mandate, but only suggest different suitable quality management systems be used, there is no obligation by the Government to cover these costs. Exceptions to this would be if the particular contract clearly mandated that ISO-9000 specifications be used, such as one with health or

safety considerations; then the requirement would be addressed by appropriate contract clauses and the cost of certification, whether fully or partially funded, would be a point of negotiation. [3]

C. EXPORT POLICY/BARRIERS

The importance of trade in the U.S. economy is vastly understated, and too often misunderstood. Since 1985, U.S. exports have almost tripled from about \$300 billion to an expected \$900 billion this year (1997). Since 1993, more than a third of our economic growth is directly related to exports, and 11.5 million jobs now depend on exports. To sell more goods and grow our economy, we must export more because 95 percent of the world's consumers live outside the United States. In order to expand exports we will use every tool we can to open foreign markets and to stand against unfair trade practices.

Charlene Barshefsky U.S. Trade Representative

With so much importance riding on exports of U.S. products, it is clear that any barriers to acceptance of these products created by non-recognition of standards used in the U.S. is detrimental to its economic well being.

Several instances have occurred recently that have had a marked effect on the acceptance of U.S. products overseas. The "CE" mark, for instance, is required on some products exported to the EU. It is not a mark of quality assurance to a standard, but one of conforming to certain legal requirements found in EU directives. [23]

The EU inadvertently gave impressions in the past that ISO-9000 certification was a requirement for doing business in Europe. Two examples were computer switches and pacemakers that had ISO-9000 named as the recommended quality system benchmark, much like the DoD recommendation of

"ISO-9000 or equivalent" systems in Government contract language. Misinterpretation of the wording in the requirements package caused accusations by American producers that the EU was using ISO-9000 standards as a technical barrier to market entry. [41]

A large impediment to trade between the U.S. and almost all other nations is the fact that the metric system of measurement has been very slow in being implemented in the U.S. This situation is most likely to get worse before it gets any better. The EU will not permit the use of dual labeling (metric and conventional units) of products entering its markets after 1 January 2000. [9] The U.S. Government has proposed efforts for conversion to the metric standard for those competing in international trade.

Association Agreements negotiated worldwide by the EU and other countries and EU Governments' subsidies toward supporting national and regional standards are evident in more third world countries today. A number of European countries and Japan have targeted their own programs that place their particular national or regional design and engineering technologies in regulations and standards that have been adopted in both Latin America and Asia. U.S. exporters have found themselves having to commit to standards from Germany, Japan, France and Britain in order to sell their products in the emerging markets of the Pacific Rim and Latin America. The U.S. Government has realized, according to their National Export Strategy reports, that they have an increased responsibility in developing an infrastructure to promote competitiveness of their

products. By building a uniform national system of technical standards that promotes confidence and credibility in the global marketplace, it may help to break down these standards barriers to equitable trade. [9]

Some officials in the EU have a differing opinion of the United States' goal of breaking down trade barriers. The following statement by Dr. Hermann Franz, chairman of the Siemens Corporation supervisory board, gives his perspective on the standardization situation.

Europe must set standards worldwide just as it did in the past. We must take care not to allow other countries to set international standards and thereby preempt the markets for themselves. European standardization is a tool for creating competitive advantage and should come to dominate the contents of international standards. [23]

Comments such as these can give an impression that "international standard" and "national well-being" have synonymous meanings.

In June of 1997, the administrations of President Clinton and the EU formulated a Mutual Recognition Agreement (MRA) which increased the market access of products relating to their inspections, testing and product certifications. The intended result of the agreement was to put the U.S. on equal footing with the EU on private sector manufacturers' testing and inspection services where the goal of "one test, accepted everywhere," would be accomplished. [9]

In order to compete, the U.S. has embarked on a strategy similar to the EU by placing standards experts of the National Institute of Standards and Technology (NIST) in some important foreign markets such as Mexico, India, Argentina and Saudi Arabia. These experts establish close working relationships

with their regulation counterparts in these countries in order to provide exchanges of information as it relates to standards-related market access. The NIST has plans to expand this program into other regions such as Brazil, Russia and China, however approval must come from Congress, where the assumption is that approval is predicated on available funding. [9]

Stephen Lowell suggests that companies can use international standards to there advantage as strategic levers to reduce trade barriers. First, international standards provide leverage against national or regional standards as restrictive trade barriers. Second, international standards allow countries to produce and sell the same products in the global market. Third, due to the rapid change in economic conditions around the world and as new trade markets emerge, those new producers complying with international standards, have easier entry to the global marketplace. [30]

1. Trade Policy Actions

In 1995, the World Trade Organization (WTO) membership grew to approximately 131 members. The entire membership is obligated to abide by the WTO's Agreement on Technical Barriers to Trade (TBT). "The TBT Agreement is the chief international trade agreement that provides binding obligations on governments in their development, adoption and application of standards (voluntary), technical regulations (mandatory) and conformity assessment procedures (procedures used to determine whether a particular product meets a standard or technical regulation)." [9]

The basic premise of the TBT is to prevent governments from using standards related measures in order to protect their domestic industries or create any kind of a barrier to free trade. Starting in 1997 and every three years afterwards, the TBT Committee meets to review implementation of its rules. During the first meeting the U.S. standards organizations voiced their concern that the structure of the TBT was such that some U.S. standards (QS-9000, ANSI/ASQC Q-9000) were not considered "international" even though their activities were conducted through open procedures and in consensus with participation of foreign nations standards bodies. Herein lies a tremendous problem. Some U.S. private sector standards are international in use and they incorporate some of the finest technological expertise found in the world. Since they may not have an "approved" rating by national standards organizations in foreign countries (members of ISO), they may not be recognized as meeting an "international standard." Without this recognition in the view of foreign purchasing organizations and a competitor fielding a similar but recognized ISO standard product, the U.S. could conceivably be shut out of lucrative markets. The TBT is supposed to remove barriers based on standards recognition but it appears that signatory members may not always abide by the rules. As mentioned earlier, the U.S. is focusing its efforts in making the MRAs with the EU a dependable instrument to open trade and penetrate markets. [9]

2. U.S. Infrastructure

The U.S. position in the global trading market is not as strong as it could be. There exists a weakness in a focused effort concerning standards and conformity. The arena is decentralized and companies compete against one another, which plays well with the U.S. competitors in the EU who have a more "focused" approach to using standardization to their economic advantage. Despite the presence of organizations such as ANSI and ASQC, the U.S. national strategy with respect to using standards to their advantage has been somewhat hampered by lack of understanding and resources.

The U.S., unlike many ISO member countries, does not provide funding for their participation in the various international standards organizations (ISO or International Electrotechnical Committee (IEC)). Industry is left on its own, resource wise, to participate. Those companies that do not have the monetary resources to participate in these organizations can be left out and their concerns may not be addressed. [9]

Similarly, those less industrially developed countries that want to join the global marketplace are even more so disadvantaged and are targeted by developed nations to be cultivated using their standardization systems.

According to Mr. Robert Cayne, president of the American Society for Quality Control (ASQC), "ISO-9000 has come to be the price of admission for doing business in Europe." Similarly, Ms. Kymberly Hockman of DuPont's Quality Management and Technology Center adds, "Ask any business person

who has given up trying to gain entry into the European market what stopped him, and he's likely to answer in code: ISO-9000." [19]

Whereas the EU guides its standardization policy off the ISO-9000 series, the U.S. has not. What the EU has done with standards could be considered industry wide, whereas the U.S. effort could be looked at in terms of only a division of a company – a segmented application in putting ISO-9000 to a more beneficial use. The ANSI/ASQC Q-9000 standard is not considered "universal" within the U.S. itself. Q-9000 is hard to apply across the board to American industries; it is geared generally toward manufacturing industries; and standards, not just ISO or ANSI/ASQC are met with some reluctance for various reasons discussed in a later chapter. [21]

3. EU Infrastructure

The EU has made strong efforts, with backing of some of their governments, in regionalizing their technological infrastructure. In dealings with the EU, one must take into consideration that Europe is a continent in economic transition where treaties and agreements are being forged to increase the members' share in the global marketplace. In doing so, the respective governments of EU countries have taken a proactive role in standardization methods, where the U.S. has been reactive in nature. [8]

The EU has also been looking very hard at the Eastern European Countries (EEC) and has realized the potential markets that presently exist or will mature in the near future. Getting a foot in the door in regards to manufacturing

standards and conformance issues puts them in a highly desirable position. The U.S. is also aware of the emerging markets in the EEC but is disadvantaged by distance, cultural demographics and a lack of organization.

D. STATISTICS

Figure 2 shows an almost 100% increase for international standards published between 1987 and 1997. This can be interpreted as increased awareness of the importance that the global business community places on standards in creating a competitive edge for themselves.

In the U.S. many companies have taken notice of the large increase in international standards being adhered to and the corresponding benefits that may result. Many U.S. companies are also beginning to require their suppliers to be certified or in compliance with ISO-9000 QMS. Between 1992

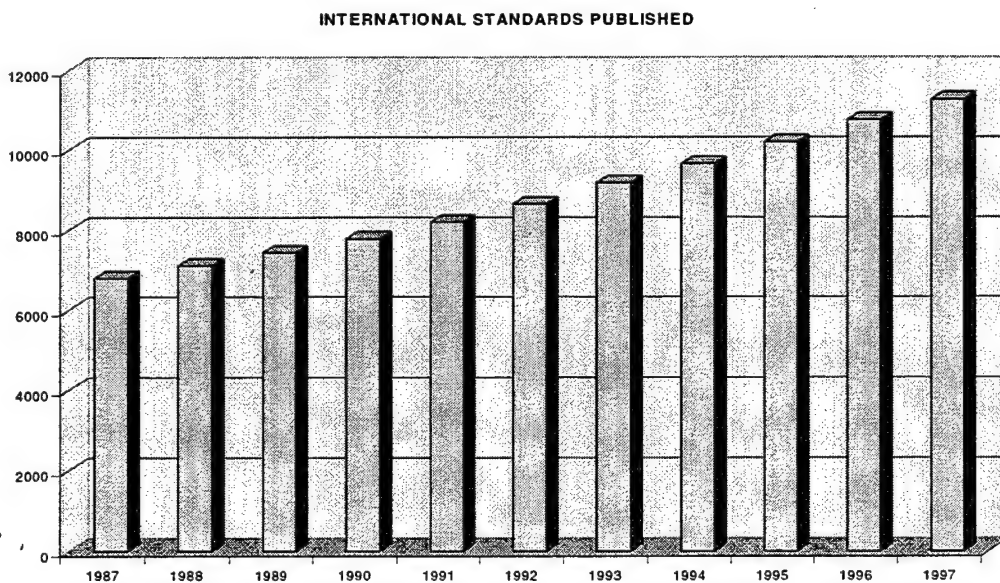


Figure 2

SOURCE: WWW.ISO.COM JAN 1998

and 1993 the number of companies becoming ISO-9000 certified increased by 500%. Through 1997, the number of companies becoming certified in the U.S. had doubled every nine to 12 months. [20] Recent estimates (Apr 98) indicate approximately 15,500 American companies have received an ISO-9000 certification. [29]

On the international front, trade agreements such as the (MRA), North American Free Trade Agreement (NAFTA) and the General Agreement on Tariffs and Trade (GATT) have also been factors in moving companies toward recognizing the importance in international standards as a competitive edge resource. At the end of 1996, 162,707 ISO-9000 certificates had been awarded in 121 countries. This was an increase of approximately 28% from the previous year. [6] Figure (3) shows the amount of ISO-9000 certifications received amongst some of the leading industrial countries during the calendar year of 1996.

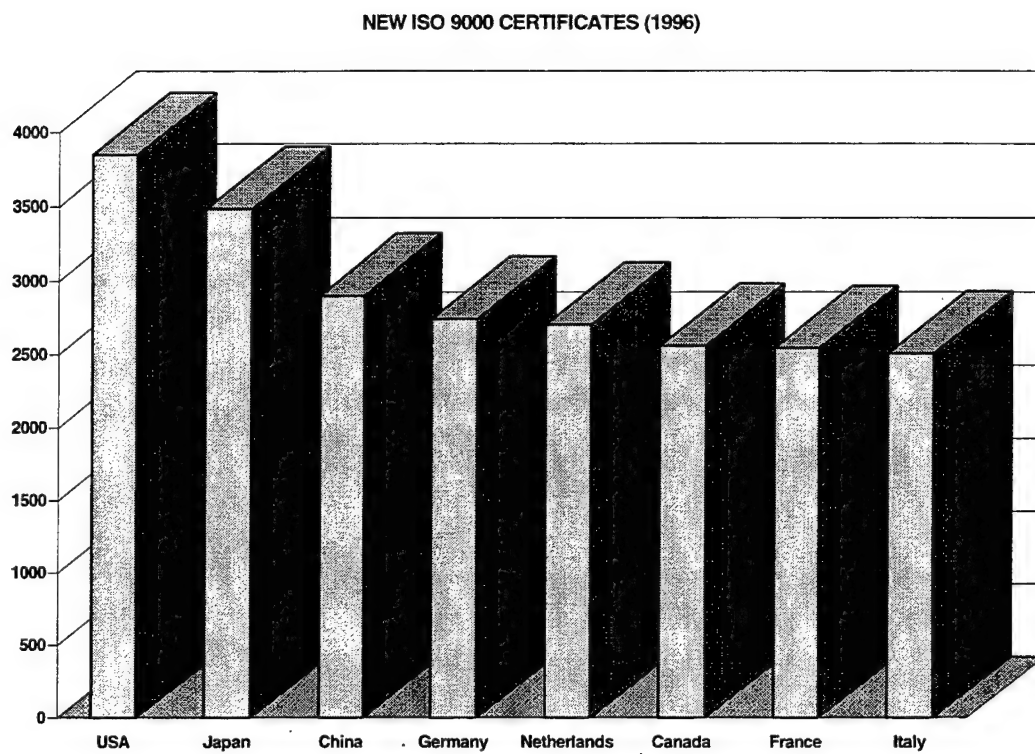


Figure 3

SOURCE: WWW.ISO.COM JAN 1998

IV. CERTIFICATION PRO/CONS

The need for certification and the costs involved in terms of money, time and personnel are the subject of some debate within the quality assurance community in industry today. Some are of the opinion that certification is unavoidable and a requirement to compete successfully. Others claim the costs do not justify the benefits received and that the registration process is somewhat skewed and susceptible to poor business practices. This chapter describes sentiments and situations on both sides of the ISO-9000 certification process.

A. PROS

Successful implementation of ISO-9000 QMS can offer several advantages to a company wishing to utilize this system as a base element in their operations. Research has shown that many companies think they are better off as a result of the time and money spent acquiring certification. Both internal and external advantages can be realized. The following areas are some of those that companies have indicated as being positive factors resulting from the ISO-9000 certification process.

1. Customer Relations & Capital

- ***An improved image in the mind of customers.*** Customer can be assured that products received have been through a good quality assurance process. [22]
- ***Better communications, record keeping and relationships with customers.*** Using the documentation process prescribed in the ISO-

9000 elements, tighter control and less error in sales administration helps to ensure cooperative relations between seller and buyer. [42]

- **Increased exports.** Those companies that do export products increase their stature in the global marketplace by joining the community of producers that follow international standards. [20]
- **Competitive advantage.** Probability of an increase in sales both domestically and in foreign markets is higher than without certification. [42]
- **High investment/payoff ratio.** ISO/Q-9000 companies surveyed (independent of author's interviews) show figures ranging between 2:1 and 4:1 returns on investment in certification. [7]
- **Reduced dependence on MIL Spec standards.** With MIL-Q-9858A and MIL-I-45208A cancelled, companies can submit their own suitable QMS in Government RFPs.

2. Production

- **Forced change helps ID problem areas.** More complete analysis of processes, as a part of ISO-9000, can determine bottlenecks faster for correction. [42]
- **Optimum resource allocation.** Following all of the elements of the ISO-9000 guidelines needed for production can optimize time, machinery, materials and personnel. Production structure changes to reduce repetitive processes. [22]

- ***Continuous improvement.*** Using the certification process as a baseline, companies can build upon this template in an ongoing manner to assess weak areas and improve those processes over time.
- ***Decrease of defective parts.*** 1997 ASQC/AIAG survey reported a reduction of approximately 54% parts-per-million in quality defects. Though not a hard figure for every company receiving certification, improved quality processes are attainable. [7]
- ***Consistency of product.*** With ISO-9000 guidelines in place, production processes will provide consistent quality products the customer can count on. [19]

3. Corporate Structure

- ***Company objectives.*** Clearly defined objectives by top management pursuant to a certification, when flowed down to supervisors and workers give better understanding of future objectives of the company.
- ***Improved internal communications.*** Use of Integrated Product Teams (IPT) or functional area steering committees for implementation of certification process opens lines on communication for other company objectives.
- ***Delegation of responsibilities.*** Certification process can increase morale when the “team-effort “ approach is used and everyone in the company shares in the responsibility of implementation.

B. CONS

Despite all of the attributes that industry says can happen when ISO-9000 certification is reached, there are detractors to the ISO-9000 standard as well. The areas below are questions and opinions that industry has raised concerning the utility of ISO-9000.

- ***No guarantee of a quality product.*** Receiving a certification does not ensure or provide any guarantee that the product or service provided is a quality product or is free from defects. It only shows that a quality system process is in place, but not necessarily being used to its capability. [26]
 - ***Just another Buzzword.*** Manfred Bender provides a suitable quote:

I have one steelmaking client who is refusing to become ISO-9000 certified. 'It is an advertising gimmick' I am told.

'Our quality-management standards are superior to ISO, and we will not belittle our standards by becoming ISO certified.

Our customers are well qualified to judge our product.' [44]
 - ***Auditor interpretation.*** There has been a tendency for auditors to assess quality systems in too fine a detail of the standards on the technical side and the easy to audit functions of a certification. [42]
- Auditors not familiar with the industry they are auditing can misinterpret functions under the standards or force their interpretations. [27]

- **No time frame for corrective action.** ISO-9000 does not specifically mandate or recommend a period of time that a recognized problem needs to be corrected. Suppliers can take as long as they wish to implement corrective action unless demanded by customers. [27]
- **Larger impact cost on small businesses.** Forced certification on small businesses wishing to sell products to large companies, who only buy from certified suppliers can cause a financial burden for the smaller company. [22]
- **Lost production time.** If correct training techniques are not supplied to the workers responsible for implementing ISO-9000 guidelines, disruption in production can result. [28]
- **Customers focus on reduced costs.** Emphasis by major buyers on reduced costs of products pressures suppliers to balance decisions of quality systems versus cost reduction. Certification costs are often allocated into products; therefore a dilemma can occur in choosing priorities. [35]
- **Bureaucracy and inflexibility.** Documentation procedures, one of ISO-9000s trademarks, create excessive paperwork and the perception that once in place, deviations from the process may disqualify recertification. [43]

C. DEBATABLE ISSUES

Some issues concerning ISO-9000 are neither pro nor con in regards to the utility of certification but bring up questions as to various aspects of the complete certification process.

- ***Anticipatory/Realized benefits.*** A 1997 University of Toledo survey of 300 ISO certified companies indicated that the top three reasons why companies wished to pursue ISO-9000 certification, in order, were quality improvement, increasing their customer base and improving their productivity. The survey showed that benefits received were more aligned to documentation improvement, improvement in standards and quality awareness. These three realized benefits can be associated with quality improvement however, the responses concerning the other two reasons that certification was pursued were significantly less. [36] In this case what was wanted and what was gotten appear to be two different things.
- ***Top-level commitment/Culture change.*** To implement an ISO-9000 style system, leadership from the higher levels of management has to invoke confidence and a sense of direction to all subordinate staffs and workers. If the true implementers are not convinced that a new process system is worthwhile and that it will entail a different culture than what they are familiar with, benefits may come at the price of low morale, confusion and disenchantment – all obstacles to better

productivity. Senior management commitment cannot wane either when certification is arrived at; it should be continuous just like improvement. [31]

- **Accreditation.** The accreditation organizations are responsible for creating the procedures and rules to be followed by registrars, certifiers and test labs. Complaints have arisen concerning accreditation boards in their sometimes-loose interpretation of the ISO-9000 standards. There is also no singular method in accrediting the registrars. This can lead to interpretive differences with companies going through the certification process. Misrepresentation of ISO-9000 by registrars is another complaint that industry has brought up and the general consensus is that over time the poor performing registrars will be weeded out or "disbarred". [40, 21] In January 1998, members of the International Accreditation Forum (IAF) signed a multilateral agreement that accreditation of registrars would be done in a comparable manner and that worldwide recognition of this agreement should follow. [16]
- **Consultants.** Consulting fees for a company wanting to become ISO-9000 certified can amount to significant sums. Rough estimate averages for the cost of an auditor can reach \$1500.00 a day plus expenses. This is the cost of the audit bill itself, not the total cost of a certification work up. [19] Some companies have complained that

these fees are prohibitively expensive; however, it may not be wise to “shop around” for the lowest priced consultant as his advice may cause interpretation disagreements with subsequent registrars. Supply and demand usually dictates a good consulting firm from a poor performer. Another concern is that the consulting industry is not regulated as the registrar industry is. [10]

V. INTERVIEWS

Chapter V provides information on the selection methodology of ISO-9000 certified companies that were interviewed for this thesis. Additionally, and more importantly, the interviewed companies' judgments and perceptions of ISO-9000 and how it has affected their businesses are brought forth.

A. BACKGROUND

Seven different companies located in the greater San Jose, California area were interviewed. All seven companies had already received an ISO-9000 series QMS certification. Resource constraints precluded the addition of non-certified companies. The limited number of companies that were chosen cannot be considered statistically significant and the opinions and answers to the interviews take that into consideration.

Two conditions of bias could have an effect on the analysis and conclusions of the researched material. Due to the geographic location and the flourishing economic conditions of this location at the time of the interviews, the opinions of the interviewed companies may not have been indicative of all U.S. companies cost/benefit situations. Having already received an ISO-9000 certification, a bias or one-sided opinion may occur in their cost/benefit judgments over companies that are not certified.

The interview selection process consisted of three major steps. First, the www.qualitydigest.com, Internet website database for ISO-9000 certified companies was chosen. Second, the Occupational Safety and Health Act

(OSHA) Standard Industrial Classification (SIC) system was referenced to identify companies that produced military related products or products that the U.S. Government would purchase. Third, once companies were listed, they were cross-referenced to the metropolitan San Jose, California area and then were contacted by telephone for interviews.

Located in the Appendix is the set of questions that were forwarded to selected companies prior to interviews being conducted. The questions were developed to mirror areas of concern and debate found in the written research material.

B. QUESTIONNAIRE RESPONSES

The seven companies interviewed produce varied products. They were:

1. Solid and liquid fueled rocket motors
2. Silicone pressure sensors
3. Electronic semi-conductors
4. Medical diagnostic devices
5. Production machinery for electronic items
6. Production machinery for semi-conductors
7. Medical-use Lasers

The responses given to questions under the general heading areas of the interview questionnaire (Appendix) are summarized to give the reader the perspective of the interviewed Quality Assurance Managers on ISO-9000 and how it has affected their business operations.

1. Company Profile

The pool of interviewed companies consisted of one (1) small company (170 employees), four (4) medium sized companies (250-600) and two (2) large sized companies (greater than 1500).

Annual sales figures ranged from \$25-30 million for the small company to \$500 million for a medium and a large company. Two companies interviewed were not able to provide annual sales figures. [14,15,17,18,31,38,39]

2. General

All of the companies interviewed had one person dedicated to implementing their quality management system and he or she was considered the "champion" of their ISO-9000 certification program. Their official titles differed very little and all could be considered Quality Assurance Managers for simplicity.

When asked whether the decision to become ISO-9000 certified was the result of customer pressure or internal factors, more than half of those interviewed responded that internal reasons dictated their decisions. Two of the companies are subsidiaries of companies that are headquartered in the EU, and the parent office expected certification. One company was directed to obtain certification as a result of a new CEO taking over and the other adopted ISO-9000 to assist its business goals of reaching sales of \$2 billion by the year 2000. Three companies maintained that customer pressure was their reason to receive certification and one of those three used ISO-9000 as a partial foundation of their

business process and has adopted the Malcolm Baldrige Award model as a quality assurance system goal. [14,15,17,18,31,38,39]

3. Implementation

The use of a teaming approach between management and workers for implementing ISO-9000 was divided nearly in half with the majority contending that worker involvement in the certification process was a vital ingredient for success. The other half designated individual business units or steering committees of senior management to work out the implementation process.

None of the companies used any form of a local network of similar companies to gain certification information. All utilized either resident expertise or independent consultants.

When going into the certification process several areas of concern were prevalent in all the companies interviewed. The largest concern was that company owners or senior managers did not fully understand the meaning or process of an ISO-9000 certification. Some of the interviewees stated that even after certification had been completed there was still a lack of understanding on the part of management that a certification was a continuous process. Excessive paperwork requirements resulting from certification was a concern common to most of the interviewees as was the idea that the workers responsible for actually using and maintaining the ISO-9000 process did not have full understanding of the standard requirements. Only one third of the companies had any concern

over cost justification. Most of the companies had made decisions beforehand to budget for the certification costs.

All seven companies received their certifications through the use of a third party registrar. To clarify the ways to become certified the following explanations are given. "First party" certification is a self-declaration by the company (producer) that their product conforms to the standard referenced against. "Second party" certification is carried out by the purchaser (buyer) of the product or service and they make the determination if the product or service is in compliance with a standard. An independent auditor verifies compliance with a standard and if so, can issue a certificate stating that the standards are met; this accomplishes "Third party" certification. [26] Each of the seven interviewees expressed the opinion that interpretive differences between the third party certifier and the company in regards to the elements of ISO-9000 were a natural occurrence, but in all instances constructive discussions and negotiations were the norm in working those problems out.

Interviewees were asked if any Total Quality Management (TQM) programs or other type of QMS were used as a parallel to their ISO-9000 program. Almost half had TQM initiatives directed internally or by their parent company and the other half of the companies expressed the opinion that TQM and ISO-9000 were complementary systems to each other and were used together in order to get the maximum benefit of both systems. One company

uses ISO-9000 in tandem with a mandated quality system from the Food and Drug Administration. [14,15,17,18,31,38,39]

4. Cost/Benefits

Somewhat expectedly, none of the seven Quality Assurance Managers interviewed could provide a hard number concerning increases in sales dollar amounts after receiving their ISO-9000 certification. However, more than half did mention that while dollar figures were difficult to determine, they had realized increases in their customer base; which is one of the predominant reasons for their decision to work for an ISO-9000 certification.

Cost of certification varied widely. One company could not provide a dollar figure but mentioned that it was "very costly" [38], while the other companies' costs ranged from \$20K to \$1Million. The average cost of a small company was \$265K, \$700K for a medium sized company and \$47K for a large company. (Again it must be noted that with a data sample of only seven, one amount considered to be an outlier can significantly distort average amounts, this appeared to be the case with the one company spending approximately \$1Million).

When asked if the cost of certification was above what they could reasonably perceive as benefits received, there was almost a resounding no. The one dissenting opinion was the one company who had spent the most money in acquiring their certification. That company's comment was that consulting costs were prohibitively expensive. The other six companies

appeared satisfied with their cost/benefit ratio. Opinions of non-monetary benefits received were consistent from company to company. The most prevalent benefit received was a disciplined documentation system of all processes. This documentation increased knowledge retention within the company, knowledge of processes that was held by individuals was now available to everyone. Other benefits resulting from their certification process were better organization of functional areas and the perception amongst the companies' customers that the products produced now, under a program of a recognized QMS such as ISO-9000, could be counted on as being consistently higher in quality than before. [14,15,17,18,31,38,39]

5. International Marketplace

Approximately three-quarters of the companies interviewed actively export their products to other nations. The same percentage had the opinion that being ISO-9000 certified had increased their competitive stature in both the domestic and global markets. Those with a dissenting opinion on this question reasoned that at one time the ISO-9000 certification may have been a competitive edge for them but as their competition also became certified, then the playing field became level once again.

Any evidence of accreditation bias, prejudice against their products by other countries despite being ISO-9000 certified, was minimal. One company, whose products are used for surgical procedures, must have the "CE" mark (explained in Chapter III, (c)) in order for it to be allowed into the EU. This is

typical of products dealing with health and safety. The two companies whose headquarters are based in the EU naturally felt no bias toward their products. [14,15,17,18,31,38,39]

6. Suppliers

The vast majority of companies interviewed did not require their vendors or suppliers to be ISO-9000 certified. The general consensus was that if a vendor had a suitable quality system in place or they were ISO-9000 compliant, their products were known to be reliable, and able to meet specifications, then their products would be purchased. However, if there should be a decision to be made concerning multiple vendors, then one who had an ISO-9000 certification would most likely get preference. Perceived performance differences of products coming from certified vs. non-certified suppliers, in the opinions of the Quality Assurance Managers, was split down the middle. Some recognized a difference, while others could not. [14,15,17,18,31,38,39]

7. Government Contracts

The movement away from MIL standards to commercial quality systems had negligible affect on the contract actions with the U.S. Government for the companies interviewed. The predominant mode of contract actions with these companies now is to sell Commercial Items (CI) to the Government, where in the past the MIL standards were used in development and production contracts. Though not actively involved with the MIL standards in their quality processes, most of the managers had the MIL-Q and MIL-I standards on hand and did

reference them on occasion. The company that manufactured rockets still uses MIL-Q-9858 in certain situations and expressed the opinion that cancellation of the MIL standard created a large vacuum since that particular standard was used for more than 30 years in their industry. None of the companies interviewed had responded to any Request for Proposals (RFP) with any alternative quality management systems other than ISO/ANSI/ASQC systems. Though some of the companies questioned were not directly involved in contract actions with the Government, all expressed their opinion that having an ISO-9000 certification would be beneficial in competing for Government contracts.

[14,15,17,18,31,38,39]

VI. DATA ANALYSIS

This chapter looks at the issue of ISO-9000 QMS and how it has affected industry and quality assurance and analyzes through researcher observation of written and personal interview sources of information. The analysis is structured in the same order as the subject material in preceding chapters.

A. OVERVIEW

QS-9000, the American version of ISO-9000 plus three additional elements, was embraced by the American automotive industry in efforts to bolster their quality consciousness. The domestic market's increasing favor toward an imported automobile was due in part to the belief that the quality and innovation of American made autos was inferior. Facing this situation and in order to remain competitive, U.S. automakers needed quality systems that would regain consumer confidence and market share. Pressure from foreign countries invading their domestic markets in essence forced U.S. industry to adopt international standards. [24]

As the quality assurance evolutionary path progresses, newer more efficient systems appear in order to create a business that can produce products in the most efficient manner possible. These new systems are used to accomplish the following objectives: using the minimal amount of workers, materials, time consumed per unit of product, and paying the lowest cost possible for materials used. Larger profits and sustainability/growth are the end results companies strive for. By using the ISO-9000 QMS model the researcher

has observed that industries can tailor their internal quality assurance in hopes of achieving those goals. ISO-9000 QMS is a voluntary tool that may provide industry with a better quality management format than ones they may currently use.

The company who had used MIL-Q-9858A for more than 30 years said that continuous improvement was the key in maintaining the ISO-9000 QMS for its semi-annual recertification audits. The research material and interviews indicated that continuous improvement of a company's QMS is an expected byproduct when adopting the ISO-9000 QMS model. Customers expect suppliers that are either ISO-9000 compliant or actually certified, to also continually improve their quality assurance systems, this opinion was clearly indicated by almost every company. However, ISO-9000 does not guarantee any kind of continuous improvement in itself. Continuous improvement can happen only through constant internal auditing and external audit entities that show where improvement needs to be taken. [26] Herein lies a point of contention for some in industry that maintain that once certification is achieved, following up and continuing the process that ISO-9000 sets forth can diminish in importance as companies concentrate on production and sales. The researcher observed that some of the interviewed companies insinuated that this frequently is the case.

B. DOD and ISO-9000

An important point must be brought forward in regards to the FAR requirements as it pertains to contract action with the Government. The

SECDEF memoranda of 29 June 1994 and 6 December 1995, and the USD (A&T) memorandum of 8 December 1995 were clear in their intent of moving to quality assurance systems other than the MIL SPEC requirements that were relied upon in the past. [33] It was not until 1 October 1996 that the military specifications MIL-Q-9858A and MIL-I-45208A were cancelled from the DoD Index of Specifications and Standards (DODISS). The DFARS was updated and now gives an all encompassing statement of the flexibility available to contractors and contracting officers in determining what type of quality management system is acceptable. FAR Part 46.2, Contract Quality Requirements, have not been updated as of October 1998 to be consistent with the above-mentioned SECDEF and USD(A&T) memos by deleting the MIL-Q-9858A and MIL-I-45208A standards recommendations from the written guidance and replacing it with ISO-9000/ANSI/ASQC-Q9000 "or equivalent" systems that are the basis of the SECDEF's guidance. [DFARS Part 246; Quality Assurance] FAR 46.202-1, Contracts for Commercial Items, only mentions vaguely that the contractor's existing quality assurance system would be relied upon as a substitute for inspections, with some exceptions.

This lack of updated wording can possibly lead to misunderstanding on the part of those individuals who use the FAR or DFARS as their predominant resources in contract formation and guidance. In the opinion of the researcher, memorandums that provide direction and guidance are credible documents and necessary to indicate leaders' intent. Although memorandums may be insightful

and visionary, the rulebooks (read FAR and/or DFARS), need to be changed in a timely manner to reflect the intent with specific written guidance that the responsible parties can use to implement the new requirements. Without this written word, intent can become altogether lost or diluted in acceptance and interpretation.

A time gap of almost three years between directed action and official documented regulation (still not accomplished) appears to give the indication that the direction has been accomplished completely or that importance of this issue is not high on priorities lists.

C. EXPORT POLICY/BARRIERS

The non-conversion to the metric system has hurt the United States. Until there is a whole-hearted conversion, trade exports to countries using the metric system will not reach their full potential. Earlier efforts to promote the metric system during the 1980's met with strong resistance from American industry. The associated costs of re-tooling, non-interchangeability of existing products using the Standard of American Engineers (SAE) system, and a deeply engrained cultural mindset in America will continue to make this changeover difficult at best. The researcher sees it as only a matter of time before the metric system is incorporated fully into U.S. industry. Those industries that do not export could conceivably decide not to convert, though with the economies of the world becoming so intertwined and markets increasingly accessible to consumers, products thought of, as being "domestic" can become global easily.

As part of their global strategy, the EU has been targeting third world countries to promote regional standardization and regulations sympathetic to the initiating country. [6] The author sees this as a type of "standardization colonialism", however, this strategy can be looked upon as a proactive attempt by companies to secure additional market share. None of the companies interviewed came across any problems associated with this strategy in marketing their products overseas.

Efforts to set regulations and regional standards through subsidization programs in third world countries narrows the scope of the concept of "unrestricted free trade" to that of "nationalistic goals comes first". Hermann Franz's quote (see Chap III (C)) puts the standardization situation in clear perspective – gaining a place in the global marketplace is a very competitive game. The countries that can project their goals through influence, such as training a prospective trade partner in use of an ISO-9000 QMS model, clearly will gain the upper hand in foreign markets. According to Mr. Grebe, the EU is determined to not let any other trade block or individual nation get ahead of them in this respect. [23] Consequently the U.S. has done much the same and is cultivating relations with respect to standards and systems in other countries as well, in hopes of increasing their markets. [9]

1. Trade Policy

The Technical Barriers to Trade (TBT) agreement was negotiated in order to neutralize advantages arising from the actions of the EU and the U.S. in

establishing those close, exclusive relationships mentioned above, and to break down barriers to trade. [9]

If member countries of ISO selectively ignore or declare that products produced under the QS-9000/Q-9000 QMS are not recognized as meeting ISO-9000 QMS criteria when one was derived from the other as opined in the literature reviewed, then the TBT appears to be a feel-good document lacking teeth.

The ISO-9000 standards, while a model for company quality assurance, may not have the intended effect of putting industry on the same plane if they are used in a way to create an advantage for one at the expense of another.

2. U.S. Infrastructure

The lack of focus on the part of U.S. industry and Government with regard to standardization and its capabilities and advantages is apparent. The five companies interviewed that do export products did not indicate any association with any of the domestic standards organizations such as ANSI or ASQC who provide input to ISO in those areas of concern for U.S. companies. Lack of direct funding for participation in those organizations that set the standards (ISO) appears to have hurt the U.S. in that they are behind in understanding what advantages international standards can provide to industry in terms of gaining market shares and competing against the more experienced (in ISO-9000) EU.

[9]

The U.S. Government's export strategy recognizes the many challenges that confront U.S. industry and understands that entering markets is considerably dependent upon utilizing international standards, but it states that resource constraints in agreement follow-ups is a consideration that needs to be taken into account. [9]

This indicates to the author that there is understanding of a considerably large and potentially harmful problem for U.S. industry. The Government may not recognize this as critically important if they profess to resource inadequacies as a reason that agreements, meant to provide some type of protection for U.S. industry, are not seen through.

3. EU Infrastructure

The EU has moved forward with its goals of using international standards, the ISO-9000 model, as a vehicle for increasing market share and entering emerging markets. European government subsidies in their efforts, contrary to the U.S. Government's efforts, appear to be paying off. [5] The EU has several advantages in the international standards area. First, the ISO started within their borders and they have a better understanding of how the standards can benefit them. Second, the opening of the EEC markets in their backyard offers the EU a tremendous advantage over the U.S. in trade due to locale and cultural similarities between the two areas. As mentioned previously, setting up regional standards relationships in the EEC by the EU could make it harder for the U.S. to enter those lucrative markets.

D. STATISTICS

The increases in internationally accepted standards and the increased numbers of companies becoming ISO-9000 certified shows that many manufacturers and providers of services have joined the global international standards community. [6] Why? They hope for a competitive advantage in both domestic and global markets that will fulfill their desires to become a proficient, efficient organization.

E. CERTIFICATION

In reviewing the sources of information for this thesis, the author came across opinions that both supported and refuted the utility of the ISO-9000 QMS. Each argument had valid examples that supported chosen sides of the argument.

The majority of the references were in favor of international standards and of ISO-9000 because the system brings some order and discipline not only to the quality process but generally to the overall business process as well.

According to the data reviewed, the overriding benefits that ISO-9000 QMS brings to a company going through the certification process is a sense of competitive advantage within their industry and the forced documentation that the ISO-9000 QMS demands. One of the interviewed companies exclaimed that in his particular industry, ISO-9000 certification is now the status quo, where as at one time, when only a few were certified, they may have enjoyed a competitive advantage over those companies not certified. Competitive advantages seem to hold as long as a company is in the minority of certified companies producing

similar products. Once all or most of the competition becomes certified, the advantages become diminished but the process of continuous improvement awareness and documentation requirements continues to be a vital part of the ongoing business operation.

The data shows that those in disagreement with ISO-9000 QMS are in the minority. The majority of those companies or individuals focus on three areas of concern; disproportionately high cost for smaller companies going through the certification process, the lack of any guarantee that follow-on continuous improvement methods would happen, and the high cost of consultation fees. It is interesting to note the one company interviewed that spent the largest amount on total certification costs, over \$1 million, was also one of the companies that was the most vocal in pronouncing that adopting the ISO-9000 QMS was one of the best decisions the company has made. Smaller companies sometimes do not have the financial resources to be able to absorb the cost of certification as easily as larger companies or subsidiaries of mega-companies. This situation can cause decisions against certification; at what other costs in the future is undeterminable.

The continuous improvement concern was looked at earlier in this chapter. Some industry customers were of the opinion that ISO-9000 QMS, once adopted, could not guarantee certain aspects of expected outcomes, and therefore the system is not good. No quality system makes any guarantees, except one that is fully automated. Quality systems must follow the procedures to be successful.

Consultation costs and audit fees were continually mentioned as a drawback to ISO-9000 QMS certification. The interviewed Quality Managers had not experienced any trouble with unqualified consultants or auditors. To the contrary, all had high praise for the certifying teams that provided the final audit for their certifications. All did mention that it was imperative to ask for an auditor or consultant that had experience in the particular industry that was being audited. The ISO itself, has recognized a problem with unscrupulous consultants, who are not regulated, charge unreasonable amounts for their work, and more importantly, may not give quality advice to a company trying to improve their quality systems. The author is of the opinion that maverick consultants can be weeded out by using smart business practices such as networking to find good, highly qualified professionals that are experts in their respective fields.

F. INTERVIEWS

The companies interviewed are all currently successful in their respective industries. All of the Quality Assurance Managers interviewed are experts in their fields and have been in the quality assurance field for many years – either in their current companies or with other companies. Previous company experience undoubtedly helped increase their understanding with respect to implementing the ISO-9000 QMS. The author attributes this expertise and understanding of quality systems as a prime factor in the successful implementation of the ISO-9000 QMS in their companies.

The reasons given for deciding to implement the ISO-9000 QMS follow closely those in the written references – to satisfy customer needs and to gain more efficiency in their quality assurance departments.

Implementation itself brought forth a prevalent concern in all of the managers interviewed and almost all of the written data arguments – that of senior management commitment and understanding of the complete concept of ISO-9000 QMS from beginning to end. Simply put, the reference data, both written and interviews, indicated that without commitment and teamwork between management and workers to implement the ISO-9000 system and fulfill the requirements of that system, it would not work for very long. The author feels that this situation, necessity of teamwork, is no different in any organization, military or civilian.

The area of accreditation bias in exporting their products is at odds with those opinions expressed in the written data. Other than one company who is required to have the "CE" mark on their exported products (health and safety) none of the companies feel there was any bias toward their products being produced under the ISO/Q-9000 systems. This could be attributable to a few reasons. One possibility may be that those companies that have come under some sort of export bias are in the minority, but are highly visible via written articles. Another possibility is that the interviewed company's products are in high demand or the customers were satisfied with the product quality regardless of the quality system resident in the company.

The cancellation of MIL-Q-9858A and MIL-I-45208A has not had a detrimental affect on the companies interviewed in their relationships with Government contracting. The one company in particular that had used the MILSPECs exclusively over many years had successfully transitioned to ISO-9000 QMS. The Quality assurance manager for this company expressed the belief that since everyone in the company was familiar with the MILSPECs, that it made the transition that much easier. These two MILSPECs do have good attributes to them, they were one of the systems for ISO-9000 formulation, and industry does have the prerogative to go back and use those areas within the MILSPEC that may benefit them. The ability to break out from restrictions imposed by MILSPECs and use ISO/Q-9000 is a plus for industry and the Government – industry has the ability to choose quality systems to meet the needs of requirements contracted for.

In conclusion, ISO-9000 QMS is an evolutionary outgrowth of previous years attempts at quality management techniques. As the world becomes a smaller place and economies of nations interact, it is natural that common, efficient systems develop giving a common denominator in the world of quality assurance.

The ISO-9000 QMS is a good system that can and does benefit those companies that are willing to go an extra step to improve themselves. There are some opinions to the contrary, with valid arguments; however, they voice the minority opinion.

VII. CONCLUSIONS AND RECOMMENDATIONS

This final chapter draws conclusions based on the primary and secondary research questions stated in Chapter I, provides recommendations and identifies areas for follow-on research.

A. CONCLUSIONS

1. Primary Research Question

Is ISO-9000 certification a necessary tool to increase a company's competitive stature in seeking out both DoD and commercial contracts or are their suitable quality process system alternatives available to industry that will ensure acceptable product quality?

As shown by the statistics in Chapter III, many companies have chosen to implement the ISO-9000 QMS because they believe it will produce a better system than the system they have previously used. ISO-9000 QMS is not an absolute necessity to become competitive in today's marketplace. The ISO-9000 QMS can help a company's position in the marketplace *ceteris paribus*. DoD guidance now encourages companies to use suitable quality systems, ISO/Q-9000 being one, and has generally removed sometimes-restrictive MILSPEC requirements from contract language, opening the door for alternative systems to be used. ISO-9000 compliant, but not certified, systems can also be a suitable quality assurance system for use in Government contracts. The end-state of any contract, be it commercial or military, is that the product must meet a certain level of performance. It is now up to the contractor to use whatever system they choose to make sure the product meets those performance specifications.

2. Secondary Research Questions

a. What is ISO-9000 and how can it benefit a company?

ISO-9000 is a quality management tool comprised of 20 systematic management standards used by a company to manage their quality processes. Benefits, when the system is applied as directed, lie in increased resource use efficiency, a marketable competitive edge (though maybe temporary) and as a vehicle for continuous improvement of their system and subsequently, the product line. A quality management system such as ISO-9000 QMS, recognized internationally as one that can produce products of credible quality, can lead to an increased opportunity outside the U.S.

b. What is the impact of ISO-9000 on Government contracting and global business?

Aside from the slow response to changing some contract publication language, the impact of ISO-9000 on Government contracting has been positive. When DoD contract guidance in 1994 lifted the MILSPEC standards as requirements for quality systems, the new guidance allowed companies who have an ISO-9000 certification or equivalent system a foot in the door should they decide to respond to an RFP. This increases the competitive pool of qualified suppliers, which benefits both the contractors and the Government. ISO-9000 QMS and its equivalents have forced the quality systems requirements in Government contracts to expand and create a much easier situation for industry.

Globally, ISO-9000 has been well received by most nations. The United States has been slow to accept the idea of "international standards," however, many companies in the U.S. have realized their competitive disadvantage and have moved in the direction of companies in other countries and have become ISO-9000 QMS certified. It appears to the researcher that nationalistic motivation for economic well being and growth, as depicted in Chap 6(c), transcends agreements and arrangements made between nations. Unless these agreements are multilaterally made into enforceable laws in the countries of the parties concerned, then companies have the latitude to conduct business in their best interests.

There can be no doubt that international competition for market share has its brutal side. It is the opinion of the author that ISO-9000 and its derivatives, present and future, in the context of meshed, interrelated global economies is the wave of the future and those not moving in that direction may be left behind.

c. What are the positive/negative factors a company must consider if choosing to adopt the ISO-9000 Quality management System (QMS)?

Major benefits of ISO-9000, when applied correctly, are documentation of all processes, continuous improvement in quality of products, recognition of a credible quality assurance system both domestically and abroad and possibly a competitive advantage in their respective market. Disadvantages of ISO-9000 QMS implementation include the relatively high cost in terms of time and

resources spent with consultants and the time that must be spent internally preparing for the certification audit.

d. What is the value to businesses that adopt the ISO-9000 QMS?

The overwhelming majority of the companies studied in the written reference material and all of the companies interviewed in the course of this thesis saw ISO-9000 QMS certification (or compliance without certification) as a very successful endeavor and helpful in promoting their companies' business objectives. The internal re-organization of the quality assurance department alone resulting from the ISO-9000 preparation was viewed as something that needed to be done in more than one company. Communicating by "yellow-stickies" in a multi-million-dollar company has the potential for trouble. When the companies interviewed for this research were asked, despite the large costs involved in implementing ISO-9000 QMS, if it was worth the trouble, pain and torment, each responded with "absolutely"!

B. RECOMMENDATIONS

The following recommendations are offered by the author and are based on the author's assessment of the written references and the interviews that were conducted.

Recommendation #1:

A time lag of over four years has occurred since the Secretary of Defense distributed a memorandum (SECDEF Memorandum of June 29, 1994) directing that Government's contract actions embrace the use of commercial practices and

performance specifications. The memorandum was specific in allowing ISO-9000 QMS as a suitable quality assurance system for contractors seeking to respond to Government RFP's to use. To this date the Federal Acquisition Regulation (FAR) Subpart 46.2 Contract Quality Requirements, has not been updated to be consistent with this guidance. The incorporation of the wording to reflect the intent of the SECDEF memorandum should be done as soon as possible to prevent confusion and possible wasted resource effort on the part of contractors and contracting officers.

Recommendation #2:

The field of study in international standards and its application to the global economic engine is tremendous in size and continually evolving. This thesis only begins to scratch the surface with a snapshot in time on ISO-9000 QMS. It is recommended that this study be used as a base for follow-on research of international standards and to track the direction that the International Organization for Standardization (ISO) will be taking into the next century. ISO has plans to update the ISO-9000 QMS format in the near future and it could conceivably have an impact on the worldwide standardization effort.

APPENDIX

COMPANY PROFILE

- ☐ Small business < 200 employees
- ☐ Medium business 200 to 1000 employees
- ☐ Large business > 1000 employees
- ☐ Management: _____ (size)
- ☐ Supervisors: _____
- ☐ Workers: _____
- ☐ Annual sales: \$ _____
- ☐ What products do you produce?

GENERAL

1. Does ISO 9000 have a champion in your company? Who?
____ Pres./CEO ____ Finance ____ Operations ____ Legal ____ Engineering
2. What value does your company place on ISO 9000? Why?
3. Do you believe that ISO 9000 certification is a result of customer pressure or as a tool to improve company operations and self-analysis?

IMPLEMENTATION

1. When developing your strategy for ISO 9000 implementation, was a teaming approach used between management and workers?
2. Did you use a local network of ISO 9000 certified companies to gather information for your certification process?
3. Which of the following areas were of concern when deciding to pursue ISO 9000 certification:
 - ☐ Owners/managers not understanding the standards
 - ☐ Inadequate funding

- ☐ Excessive paperwork requirements imposed by standards
 - ☐ Cost justification
 - ☐ Human resources not available or did not understand the standards
4. Did 1st/2nd or 3rd party do certification?
 5. If a third party auditing was done, did you encounter any problems with auditor interpretation of requirements and your company's interpretations?
 6. Do you use ISO 9000 system in parallel with TQM or other types of Quality Management Systems?

COSTS/BENEFITS

1. What are your estimated sales increases resulting from certification?
2. What is your estimated cost per employee of ISO 9000 certification?
3. Do you now consider registration too costly for what you have received?
4. What areas in benefits received, other than monetary, would you say have come about from ISO 9000 certification?

INTERNATIONAL MARKETPLACE

1. Do you export your products?
2. Does ISO 9000 certification increase your competitive stature in domestic and global competition?
3. Have you seen any evidence of accreditation bias in trying to export your products?

SUPPLIERS

1. Do you require your vendors/suppliers to be ISO 9000 certified?
2. Do you see any differences in performance of your suppliers that are ISO 9000 certified?
3. Does ISO 9000 certification influence your choices of suppliers? Why or Why not?

GOVERNMENT CONTRACTS

1. Has the Government's initiative to shift from military quality standards to commercial (ISO/ANSI/ASQC) standards affected your contract dealings with the DOD? To what extent? Please explain.
2. Do you still use MIL-Q-9858 or MIL-I-45208 specs in some situations? If so please provide examples.
3. In recent contract actions, have you provided to the Government an alternative quality system, other than ISO/ANSI/ASQC, that was considered acceptable in an RFP?
4. Do you view ISO 9000 certification as a "must" to compete in Government contracts? Why?

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